



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/744,846 | 05/24/2001 | Jacques-Pierre Moreau | 00537-182002 | 5083 |

7590

09/20/2002

Brian R Morrill
Biomeasure Incorporated
27 Maple Street
Milford, MA 01757

| |
|----------|
| EXAMINER |
|----------|

BORIN, MICHAEL L

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1631

DATE MAILED: 09/20/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,846

Applicant(s)

Moreau

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 22, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5,6 6) ☐ Other:

Art Unit: 1631

Part III DETAILED ACTION

Status of the claims

Response to restriction requirement filed 7/22/02 (Paper #9) is acknowledged. Applicant elected with traverse Group I, claim 5. The traverse is moot because claims 1-4 are canceled. Claim 5 is under consideration.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. . .

Claim 5 is rejected under 35 U.S.C. 102(b) as anticipated by Coy et al (US 4,853,371) or Bogden (US 5,411,943).

Coy

Coy teaches a pharmaceutical composition comprising a therapeutically effective amount of the compound of formula β -D-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH₂ or its pharmaceutically acceptable salt. See claims 1,3. The pharmaceutically acceptable salt can be acetate. See col. 3, line 48.

Bogden

Art Unit: 1631

Bogden teaches the use of the same somatostatin analog, β -D-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH₂, as described in Coy above, for hepatoma treatment. The somatostatin analog can be in a form of acetate salt (col. 4, line 15) and be used in a form of a pharmaceutical formulation comprising a pharmaceutically acceptable carrier (col. 7, lines 15-23).

The referenced pharmaceutical compositions of Coy or Bogden anticipate the instantly claimed pharmaceutical composition comprising an effective amount of acetate salt of β -D-Nal-Cys-Tyr-D-Trp-Lys-Val-Cys-Thr-NH₂ and a pharmaceutically acceptable carrier. In regard to intended use of the composition, it is accepted by courts that arguments related to the intended use of the composition are of little relevance in determining the patentability of the composition. See, e.g., *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to

Serial Number: 09/744846

Page 4

Art Unit: 1631

5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

September 17, 2002

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.